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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 08/952,368 | 11/17/97 | PHIPPS | J ARC2426CIP |

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QM32/0728

EXAMINER

SADULA, J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3763

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DATE MAILED: 07/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/952,368

Applicant(s)
PHIPPS et al.

Examiner
Jennifer R. Sadula

Group Art Unit
3763



☒ Responsive to communication(s) filed on Nov 17, 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-26 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-26 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

1. As per applicant's arguments the election/restriction requirements of the previous office action have been withdrawn and all claims have been examined. Examiner thanks the applicant for pointing out the deficiency.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 6-16, 18-21 and 24-26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tapper ('927). Tapper teaches an iontophoretic treatment system wherein electrical treatment current is periodically delivered at low frequencies around the range of 10 Hz, but not limited to frequencies so low. A multitude of drugs are taught capable of being delivered by such a system, most specifically insulin yet the device is able to "deliver drugs embodying large

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and/or heavy molecular structures” (5:41-47). Preparatory drugs may be infused for the use of higher current in the system. Dosage manipulation systems and structure are clearly taught.

5. It is well settled that every waveform has as many or as few segments as one wishes to define. It is further well settled that such segments may start and begin wherever and whenever one of ordinary skill wishes to interpret them. Clearly it is inherent that the magnitudes and current averages, as specified by the applicant, are indeed inherently taught by Tapper as the frequencies and methods of treatment are understood to be the same as the applicants.

Additionally, the applicant is claiming mathematical calculations of the raw data contributed by the procedure as specified. Such is inherently taught by the patent of Tapper if one is willing to analyze the data as such.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 4-5, 17 and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tapper ('927) in view of Chien et al. ('975) or alternatively Theeuwes et al. ('017). Tapper teaches the method and device substantially as disclosed however fails to adequately teach the use of fentanyl or goserelin as the therapeutic agent. Both are well known to treat pain- recently utilized in treatment of pain of cancer patients. Chien teaches the use of a multitude of different drugs such as anti-neoplastics, anti-hypertensives, narcotic analgesics, antibiotics and non-steroidal anti-arthritic drugs. Clearly the drugs fentanyl and goserelin are anticipated by this as understood by anyone of ordinary skill in the art, however it is understood by the examiner that support for such may need be placed upon record. Therefore, alternatively these claims are anticipated by Tapper in view of Theeuwes. This additional reference clearly teaches the iontophoretic delivery of goserelin or fentanyl or like drugs. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to make or use the device of Tapper with such drugs of Theeuwes as it is taught by Tapper that the device is able to "deliver drugs embodying large and/or heavy molecular structures" (5:41-47) and such drugs would indeed be classified as such but would be specific to cancer patients needs.

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Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Tapper ('794) teaches additional waveforms and specification of the manipulation of such as taught by the applicant.
- b. Murdock ('383) and Lattin et al. ('155) both teach the iontophoresis drugs utilized by the applicant

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer R. Sadula whose telephone number is (703) 308-2977. The examiner can normally be reached on Monday- Thursday from 9am to 6pm. The examiner can also be reached on alternate Fridays.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Wood Coggins, can be reached on (703)308-1344. The fax phone number for this art unit is (703) 308-0758.

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.



Jennifer R. Sadula
18 July 1999

WYNN WOOD COGGINS
SUPERVISORY PATENT EXAMINER

